

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of: Michael Hagen  
Application No.: 10/009,473      Group Art No.: 1648  
Filed: November 8, 2001      Examiner: Emily Le  
For: Adjuvant Combination Formulations  
Confirmation No.: 3152  
Customer Number: 25291



Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

1. Preliminary Statements

In accordance with 37 CFR 1.97 and 1.98, Applicants submit herewith patents, publications, or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) the information is material to the examination of this application; (iii) additional information material to the examination of this application does not exist; (iv) the information, protocols, results and the like reported by third parties are accurate or enabling; or (v) the information constitutes prior art to the subject invention.

**CERTIFICATE OF MAILING 37 CFR §1.10**

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number ER672185124US addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

April 6, 2006  
Date

RoseAnn Jastrow  
RoseAnn Jastrow

2. Identification of Time of Filing

This Information Disclosure Statement

- a. ☐ is filed within three months of the filing date of the application.
- b. ☐ is filed before the mailing date of a first Office Action on the merits.
- c. ☒ is filed before the mailing date of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- d. ☐ is filed after the period specified in 2(a), 2(b) or 2(c) above, but before the mailing date of a final action under 37 CFR 1.311. This statement includes a certification under 37 CFR 1.97(e) or the fee set forth in 37 CFR 1.17(p).
- e. ☐ is filed after the mailing date of a final action or Notice of Allowance but before payment of the issue fee. This statement includes (i) a certification under 37 CFR 1.97(e), and (ii) the fee set forth in 37 CFR 1.17(p).

3. ☐ Certification under 37 CFR 1.97(e) and 1.704(d)  
The undersigned attorney certifies

- a. ☐ that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement, or
- b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the statement.
- c. ☐ certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign application patent office in a counterpart foreign application and was not received by any individual designated in 37 CFR 1.56(c) more than thirty (30) days prior to the filing of the statement.

4. ☒ Newly Cited Information  
A legible copy of the patents, publications or other information cited on the attached form PTO 1449 is enclosed, except that no copy of a pending U.S. application is enclosed, and if this patent application was filed or entered the national stage after June 30, 2003, no copy of a U.S. patent or U.S. patent application publication is enclosed.

5. ☐ Previously Cited Information  
No copy of the patents, publications or other information cited on the attached form PTO-1449 is enclosed because it has been previously cited by or submitted to the Office in a prior application which is relied upon for an earlier filing date under 35 USC 120.  
Prior application is Application Number \_\_\_\_\_, filed on \_\_\_\_\_ of \_\_\_\_\_ for \_\_\_\_\_

6. ☐ Concise Explanation  
Documents cited above which are not in the English Language
- a. ☐ have been explained in the specification.
- b. ☐ have an abstract (or other concise explanation) in English enclosed or if readily available a translation into English of the document is enclosed.

Form PTO-1449 is enclosed in duplicate.

7. ☐ Fees  
☐ Fee for filing under 37 CFR 1.97(c) or (d)      Fee:

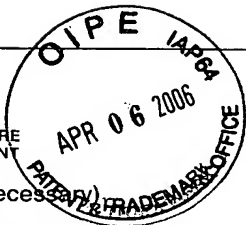
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| Substitute for form 1449/PTO<br>INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br>(use as many sheets as necessary) |   |    |   | <b>Complete if Known</b> |                  |
|   |   |    |   | Application Number       | 10/009,473       |
|   |   |    |   | Filing Date              | November 8, 2001 |
|   |   |    |   | First Named Inventor     | Michael Hagen    |
|   |   |    |   | Group Art Unit           | 1648             |
|   |   |    |   | Examiner Name            | Emily Le         |
|   |   |    |   | Attorney Docket Number   | ACY33482-00      |
| Sheet   | 1 | of | 1 |                          |                  |



| U.S. PATENT DOCUMENTS |          |                      |                      |   |  |   |
|-----------------------|----------|----------------------|----------------------|---|--|---|
| Examiner Initials*    | Cite No. | U.S. Patent Document |                      | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|                       |          | Number (If known)    | Kind Code (If Known) |   |  |   |
|                       | 1.       | 5,057,540            |                      | Kensil, Charlotte A.                            | 10-15-1991                                       |   |

| FOREIGN PATENT DOCUMENTS |          |                         |        |                      |   |  |   |                          |
|--------------------------|----------|-------------------------|--------|----------------------|---|--|---|--------------------------|
| Examiner Initials*       | Cite No. | Foreign Patent Document |        |                      | Name of Patentee or Applicant of Cited document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T                        |
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| OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS |          |  |  |  |                          |
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|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.